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COMPARATIVE STUDY OF ORAL AND VAGINAL MISOPROSTOL FOR MEDICAL EVACUATION IN INCOMPLETE MISCARRIAGE

Sunita Hemani [1] | Lata Rajoria [2] | Ravindra Khinchi [3]

[1] Assistant Professor, Department of Obstetrics and Gynaecology, S.M.S. Medical College, Jaipur.
[2] Professor and Head, Department of Obstetrics and Gynaecology, S.M.S. Medical College, Jaipur.
[3] 3rd Year PG Student, Department of Obstetrics and Gynaecology, S.M.S. Medical College, Jaipur.

ABSTRACT

Objectives: To compare the effectiveness, side effects and patient acceptability of oral vs vaginal route of administration of misoprostol for medical evacuation in first trimester incomplete abortion.

Methods: This prospective randomized comparative study was conducted on 200 women with spontaneous incomplete first trimester pregnancy loss. They were distributed in two groups receiving 800 micrograms of misoprostol; vaginally in the first group and orally in the second group. Amount of bleeding, duration of time for complete evacuation and side effects were noted and data statistically analysed using chi-square test and student t-test.

Results: No statistically significant difference was observed in the percentage of women who had complete evacuation following the use of misoprostol by the two routes. The duration from administration of drug to complete evacuation was 6.65+/- 1.05 hours in vaginal route and 6.68+/- 1.19 hours in oral route; this difference is not statistically significant. Only 6% women in vaginal route reported diarrhoea as compared to 59% in oral route and this difference is significant. Other side effects were rare and same in both groups.

Conclusion: vaginally and orally administered misoprostol are equally efficacious in first trimester incomplete abortion, but vaginal route has fewer side effects and better patient acceptability.

KEYWORDS: incomplete abortion, misoprostol, vaginal route, oral route

INTRODUCTION:

Incomplete abortion is the termination of pregnancy before the period of viability in which parts of products of conception are retained in the uterus. Incomplete abortions in the first trimester are a common entity worldwide and a cause of physical and emotional trauma for women. Surgical evacuation always carries an element of risk including infections, trauma, perforations, increased bleeding and hazards of anaesthesia[1]. Expectant management of incomplete abortion has been advocated in some studies[2]. Though effective, it is associated with prolonged bleeding and spotting which is unacceptable to most women. Medical treatment has been used since past decade in management of incomplete abortion[3,4]. There is a plethora of different combinations of medical treatment regimes for the management of incomplete miscarriage.

Synthetic prostaglandin E_1 analogue, misoprostol is a safe, effective, acceptable and affordable medical management for first trimester incomplete abortion[5]. A dose of 800 micrograms is advocated either orally or vaginally. Misoprostol causes myometrial contraction by interacting with specific receptors on myometrial cells due to change in calcium level resulting in cervical softening and uterine contraction[6,7]. Due to uterine contractions, constriction of spiral arterioles leads to ischemic necrosis of decidua and embryonic detachment which in turn leads to fall in hCG and progesterone levels secreted by trophoblastic tissues and thereby expulsion of uterine contents[8,9]. It saves women from complications of surgical evacuation like perforation or sepsis[10] and saves operative expenditure[11]. It has many routes of administration like oral, vaginal or rectal. This study was undertaken to compare the efficacy and side effects profile of oral and vaginal routes for misoprostol.

MATERIAL AND METHODS:

The present study was a prospective randomized comparative study conducted on 200 women with spontaneous incomplete first trimester pregnancy loss confirmed by transvaginal ultrasonography with evidence of retained products of conception. Patients with severe blood loss, sepsis, known allergy to prostaglandin and history of asthma were excluded from the study. A detailed history was taken and general physical and per abdominal and per vaginal examination was done on all women. After taking informed consent, the women were randomly distributed in two groups. A detailed history was taken and general physical examination and per-abdominal and per-vaginal examination was done on all the women. A complete blood count and ABO and Rh grouping was also done. Group A consisted of 100 women who received tablet misoprostol 800 micrograms per vaginally followed by 400 micrograms after four hours. In Group B, there were 100 women who received 800 micrograms of misoprostol orally followed by 400 micrograms after 4 hours.

The patients were followed for amount of bleeding and duration of time between misoprostol administration to expulsion of retained products. Side effects in the form of nausea, vomiting, diarrhoea, headache, fever and epigastric pain were noted. Ultrasound was repeated after 24 hours for evidence of complete abortion. If retained products were present, surgical evacuation was done and these cases were considered as failures.

Data were statistically analysed using chi square test for comparison pf proportions and students t- test for comparison of mean values between the groups.

RESULTS:

All the enrolled women completed the study. Both the groups matched for age, socioeconomic profile, literacy, residence and religion. Most of the women in the two groups belonged to the age group 20-30 years and around 50% of women in the two groups were primigravida. 29% of all the cases had gestational age < 8 weeks whereas 71% were between 8-12 weeks.

The success rate as determined by complete evacuation and no need for surgical evacuation was almost similar in the two groups. It was 59% when all the patients were considered as a whole. It was 58% in group A (those who received misoprostol pervaginally) whereas it was 60% in those taking the drug orally. This difference in the two groups was not statistically significant (p value- 0.886). 42 patients in group A and 40 from Group B required surgical evacuation. The time taken from administration of drug to complete evacuation was almost similar in two groups. It was 6.65+/- 1.05 hours in Group A and 6.68+/- 1.14 hours in Group B. When this duration was compared by application of unpaired t-test, this difference was not found statistically significant (p value- 0.882). When the treatment success was compared in different age groups, it was found that among the women >30 years of age there was 100% success in Group A while it was 66.7% in group B. The success rate was almost similar in other age groups.

If success rate was compared with parity, it was found to be 56% in group A and 60% in group B in nulliparous women. In para 3 and above, there was 100% success in Group A and 55.55% in Group B. None of the difference is statistically significant.

When gestational age < 8 weeks is taken into consideration, the failure percentage is 25.8% in vaginal administration group while it was 40.74% in oral group. However, the failure rate in Group A increased and was 49.27% in women with incomplete abortion at 8 -12 weeks. In Group B , the failure rate remained almost the same as in < 8 weeks (39.72%).

The difference in the pre and post treatment Haemoglobin level in Group A was 0.52 gm/dl and that in Group B is 0.54gm/dl. When these two values were compared, the difference was not found to be statistically significant. Significant

blood loss (fall in haemoglobin > 1 gm/dl) was seen in 8 women of Group A and 9 women of Group B.

If side effects of the two drugs were compared, incidence of vomiting was almost same in the two groups. However , there was a statistically significant difference in the incidence of diarrhoea. Only 6 women who were administered the drug vaginally had diarrhoea as compared to 59 in the oral group (p value < 0.001) .

DISCUSSION:

This randomized comparative study found out that both the routes of misoprostol administration were equally efficacious for evacuation in incomplete abortion . The drug to abortion interval was around 6.6 hours in both groups. Pang et al in their study had found out that the drug to abortion interval was 7.7 hours in both vaginal and oral misoprostol[12]. Mean admission Haemoglobin level was 10.52 and 10.31 in the two groups respectively while it was 12.6 and 12.4 gm/dl in the study by Pang et al[12]. This can be attributed to the fact that anaemia is widely prevalent among Indian women.

Diarrhoea was the most common side effect in group B . Similar results were observed by Pang et al where incidence of diarrhoea was increased when misoprostol was administered orally[12]. Banashree Bhadra[13] observed no increased incidence of diarrhoea with oral misoprostol. Nausea was the most common side effect observed. Crenin et al[14] reported that vomiting occurred in 30% women in oral misoprostol group and 13% in vaginal misoprostol group and diarrhoea in 50% and 38% respectively. Zeiman et al[15] compared the absorption kinetics of misoprostol with oral and vaginal routes and found that peak plasma concentration of oral misoprostol was 1.6 times higher as compared to vaginal administration and that was believed to be the cause of increased side effects.

This study emphasises the efficacy of both oral and vaginal routes of misoprostol for evacuation in incomplete abortion with lesser blood loss and fewer side effects.

CONCLUSION:

Misoprostol is an effective drug for management of incomplete abortion , given by any route –oral or vaginal. However the side effects are low in the vaginal route hence it can be the route of choice. It decreases the need for surgical evacuation and hence the burden on hospital and inconvenience to the patient.

Table 1

Age group	Group A		Group A		Group B		Group B		P value
(years)	success	%	failure	%	success	%	Failure	%	
< 20	0	0	0	0	0	0	1	100	NA
20-25	24	53.33	21	46.66	19	59.37	13	40.62	0.769
26-30	24	53.33	21	46.66	25	58.13	18	41.86	0.811
31-35	2	100	0	0	12	70.58	5	29.41	0.329
>35	8	100	0	0	4	57.14	3	42.85	0.329
Total	58		42		60		40		

Table 2

Parity	Group A		Group A		Group B		Group B		P value
	success	%	failure	%	success	%	Failure	%	
P0	28	56	22	44	24	60	16	40	
P1	10	43.47	13	56.52	23	69.69	10	30.30	
P2	15	68.18	7	31.81	8	44.44	10	55.55	
P3	4	100	0	0	4	50	4	50	0.329
P4	1	100	0	0	1	100	0	0	
Total	58		42		60		40	0	0.329

Table 3

Period of gestation	Group A		Group A		Group B		Group B		P value
	success	%	failure	%	success	%	Failure	%	
<8 weeks n=58	23	74.19	8	25.8	16	59.25	11	40.74	0.353
8-12 weeks n=142	35	50.72	34	49.27	44	60.27	29	39.72	0.329

Table 4

Side effects	Total n=200		Group A n=100		Group B n=100		P value
	No.	%	No.	%	No.	%	
Nausea	13	6.50	6	6	7	7	1.000
Vomiting	4	2.00	0	0	4	4	0.130
Diarrhoea	65	32.50	6	6	59	59	<0.001
fever	12	6.00	8	8	4	4	0.372

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